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| 10/632,878 | 08/01/2003 | Cohava Gelber | PDC 126 | 3037 |

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EXAMINER

CHISM, BILLY D

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| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,878

Applicant(s)

GELBER ET AL.

Examiner

B. Dell Chism

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. This non-final office action is in response to Applicant's papers filed 23 November 2005.

Claims 1-36 are pending and under consideration.

Withdrawal of Objections and Rejections

2. The rejections and/or objections made in the prior office action filed 23 August 2005, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 23 November 2005 will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. (Maintained) Rejection of Claims 1-6, 8-18, 20-24, 26, 28, and 33-36 under 35

U.S.C. 102(b) as being anticipated by US 6,107,497 ('497) (previously cited). The '497 patent teaches calcitonin complexed with diketopiperazine (DKP) for delivery to pulmonary tissues for increased transport of the active agents across the membranes of the pulmonary tissues.

Calcitonin is taught by the instant claims (claim 6, for example) in complex with DKP for delivery to pulmonary tissues. The '497 patent teaches the calcitonin encapsulated with the DKP

Art Unit: 1654

microparticles. DKP is a transport enhancer and as being part of the administered compounds of the '497 patent, the DKP would inherently increase the transport of the compound of the '497 patent, since the compound of the '497 patent is a claimed compound of the instant application. The '497 compound meets the physical characteristics as put forth in the instant claims. The instant claims require that the components be complexed which is the case in the '497 patent. For example, the instant application doesn't require a covalent binding between the active agent and the DKP for the complex to be formed. Therefore, the compounds of the '497 patent are no different than the instantly claimed compounds with regards to scope and therefor the '497 compounds anticipate the instantly claimed inventions. With regards to the immune response, the '497 patent only addresses the issue of intentionally increasing the immune response when there is an antigen involved as the active agent. There is no mention of immunological issues outside of that specific arrangement of components in that one possible composition (column 9). Therefore, it is inferred that there are not particular concerns with immunological responses in the '497 patent when one of skill in the art is using the calcitonin/DKP compound of '497 which is also instantly claimed. The '497 patent clearly teaches an oral administration of the compound (see column 10). Applicants' claim that the element of enhanced uptake is not addressed by this application, and that the rejection based on inherency is not sufficient since it is well established that the mere possibility something may occur is not sufficient. In addressing this argument, the examiner would like to clarify that the phrasing of the claim language is "enhancing transport". As stated above the compound taught in '497 is the compound as instantly claimed. The '497 compound is calcitonin encapsulated by DKP microparticles for transport to pulmonary tissues via inhalation or oral administration. If the same compound is taught and used as instantly

Art Unit: 1654

claimed, then inherently, the compounds would share the same bio-effecting characteristics. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." The rejection is not based on a mere probability or possibility that a particular result could happen. The rejection is not based on what would result due to optimization of conditions. The rejection is based on the fact that the method steps are the same including the compound as instantly claimed. One of ordinary skill in the art would see that the two compounds of the '497 and the instant claims, respectively, would inherently have the same characteristics. The '497 patent teaches the instantly claimed method steps and compounds used therein; therefore, the claims are anticipated. Despite the argument that the lungs are lined with a mucosa lining, it is noted that anything passing into the lungs would initially contact the lining, however, this does not serve as stopping point for the encapsulated compound in reaching the pulmonary tissue via the membrane transport. The oral administration as taught by the '497 patent would not necessarily be inhaled as the powder would be. Additionally, the instant specification teaches the same preferred embodiment of inhalation of the compound (see specification at page 11) wherein the compound would necessarily contact the mucosa lining of the lungs as is correctly pointed out by the applicants' response.

Art Unit: 1654

5. (Maintained) Rejection of Claims 1-6, 8-18, 20-24, 26, 28, and 33-36 rejected under 35 U.S.C. 102(e) as being anticipated by US 6,652,885 B2 ('885) (cited in the previous office action). The '885 patent teaches DKP/insulin compounds encapsulated with DKP microparticles for pulmonary membrane transport wherein DKP is a known transport enhancer. Administration can be via inhalation or oral, among others. The instant specification and claims teach the same compound as taught by the '885 patent. As argued above, this compound would necessarily have the same characteristics of bioactivity, i.e. transport enhancement, size, weight, etc...

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(New) Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over '497 in combination with '885 (both cited above and in the previous office action). Both references teach compounds comprising an active agent encapsulated by DKP microparticles for administration for active targeting of pulmonary tissue targeting wherein the compounds maybe administered via inhalation or orally. The compounds and methods are taught in the '497 and '885. One of ordinary skill in the art would expect success of the methods taught in '497 and '885. Therefore, one of ordinary skill would be motivated to use the instantly claimed methods because it is obvious in the teachings of the prior art, i.e. '497 and '885, which the methods work for the claimed purposes. It would have been obvious to one skilled in the art at the time of invention to determine all operable and optimum component ratios, doses, rates of

Art Unit: 1654

administration, etc... for the claimed composition of the instant application, because the component ratios, doses, rates of administration, etc... are an art-recognized result-effective variable that is routinely determined and optimized in the composition/pharmaceutical arts.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. (New) Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 claims a dose of the compound between 500 and 1000 milligrams per administration; however, this is not disclosed in the specification. The specification discloses for inhaled compound that the dose should be between 500-1000 micrograms, not milligrams. It is unclear as to which is the correct dose to be administered.

Conclusion

9. No claims are allowed.

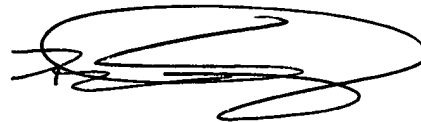
Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained

Art Unit: 1654

from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDC

A handwritten signature in black ink, appearing to read 'B. Dell Chism', enclosed within a large, loopy oval shape.

**B. DELL CHISM
PATENT EXAMINER**